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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/931,397 | 08/16/2001 | Clayton Ericson | T8273 | 3898 |

7590 10/15/2002

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| EXAMINER |
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RUSSEL, JEFFREY E

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 10/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,397

Applicant(s)

ERICSON ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1654

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In *re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In *re Clinton*, 188 USPQ 365, 367 (CCPA 1976); In *re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

2. Claims 1-3, 12, 13, 17, 23, and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/48648. The WO Patent Application '648 teaches

Art Unit: 1654

compositions comprising Ferrocel, which is an iron glycine chelate having a glycine:iron molar ratio of 2:1; an organic acid such as citric acid, malic acid, lactic acid, acetic acid, and Vitamin C (i.e. ascorbic acid); and a sugar such as sucrose. The organic acids prevent the iron source from generating undesired off-colors. The compositions can be prepared by dry blending followed by hydration, but also can be formed by spray drying. See, e.g., page 12, lines 1-34; page 13, lines 26-36; page 15, line 7-11; Examples 3, 5-12; and claims 20-29. Because the method steps and the final composition are the same, inherently the solubility of the iron amino acid chelates will be enhanced to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the WO Patent Application '648 and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than that of the WO Patent Application '648.

3. Claims 4-9, 11, 14-16, 18-22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/48648. Application of the WO Patent Application '648 is the same as in the above rejection of claims 1-3, 12, 13, 17, 23, and 26-28. The WO Patent Application '648 does not teach Applicants' claimed solubilizing agent:iron content weight ratios and sugar content:iron content weight ratios, and does not teach the order of combining components specified in instant claims 14-16. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal weight ratios of the components present in the compositions of the WO Patent Application '648 because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the beverage and food arts. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to alter the order of

Art Unit: 1654

combining components in the method of the WO Patent Application '648 because the WO Patent Application '648 teaches that a variety of means can be used to prepare the compositions, because selection of any order of mixing ingredients is prima facie obvious (see MPEP 2144.04(IV)(C)), and because the same composition appears to form regardless of the order chosen.

4. Claims 1, 3, 4, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pederson et al (U.S. Patent No. 5,516,925). Pederson et al teach forming iron(III)lysyl glycerophosphate in an aqueous solution, and then adding malic acid. The weight ratio of malic acid:iron is about 2.4:1. See, e.g., column 11, Example 8.

5. Claims 3, 7, 8, 10, 14 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Pederson et al (U.S. Patent No. 5,516,925). Application of Pederson et al is the same as in the above rejection of claims 1, 3, 4, and 9. More generally, Pederson et al disclose preferred organic acids which are citric acid, succinic acid, and lactic acid (see, e.g., column 6, lines 20-22), but do not teach the combination of these acids with an iron amino acid chelate. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the iron amino acid chelates of Pederson et al using citric acid, succinic acid, or lactic acid because Pederson et al disclose these acids to be useful in improving the palatability of amino acid chelates, and because the substitution of one known functional equivalent for another is prima facie obvious. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal component ratios for the organic acids and the iron of Pederson et al because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the beverage and food arts.

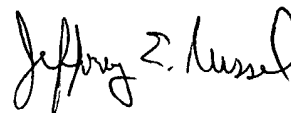
Art Unit: 1654

Pederson et al disclose adding malic acid to the solution of iron(III) lysyl glycerophosphate, but do not teach whether the malic acid is in dry or aqueous form. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to add the malic acid of Pederson et al in either dry or aqueous form, because this reflects merely an alteration in the order of combining components which is prima facie obvious (see MPEP 2144.04(IV)(C)), and because the same composition appears to form regardless of the order chosen.

6. Hsu (U.S. Patent No. 5,04,055) and Ashmead (U.S. Patent NO. 4,830,716) have been carefully considered, but are not deemed to teach or suggest the instant claimed invention because the references combine an organic acid with an iron salt and an amino acid before the iron amino acid chelate is formed, whereas Applicants' claims require the iron amino acid chelate already to exist before combination with the organic acid.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
October 2, 2002